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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/325,095	06/03/99	HILES I	LUD5246.4JEL

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HM12/0227

EXAMINER	
HINES,J	
ART UNIT	**PAPER NUMBER**
1645	9

DATE MAILED: 02/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/325,095	Hiles et al.
Examiner	**Group Art Unit**
Ja-Na Hines	1645

☒ Responsive to communication(s) filed on *Dec 11, 2000*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *27-36* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *27-36* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Amendment Entry

1. The amendment filed December 11, 2000 has been entered. Claims 35-36 have been amended and entered. Claims 27-36 are pending.

Drawings

2. Applicant is required to submit a proposed drawing correction in reply to this Office action as cited in on the PTO-form 948. However, formal correction of the noted defect can be deferred until the application is allowed by the examiner.

Claim Objections

3. Claim 35 is objected to because of the informalities is withdrawn in view of applicants amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 27-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description sets forth the nucleic acid molecules recited in SEQ ID NO: 12, 14-18, 21-22, 24-25, 27 and 29 and nothing more.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115). Thus, the structure of nucleic acid molecules is not defined. With the exception of SEQ ID NO's found in claims 32 or 33 the skilled artisan cannot envision the detailed structure of the encompassed nucleic acid molecules and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method for determining expression. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of expression. The nucleic acid itself is required. See *Fiers v.*

Revel, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, *In The Reagents of the University of California v. Eli Lilly*, (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of SEQ ID NO's, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a nucleic acid molecule...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

However, no disclosure, beyond the mere mention of nucleic acid molecules is made in the specification. This is insufficient to support the generic claims as provided by the Interim Written Description Guildlines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

Therefore only an isolated nucleic acid molecule comprising a nucleic acid sequence consisting of SEQ ID NO:12, 14-18, 21-22, 24-25, 27 or 29, but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph.

5. Claims 27-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods which use any nucleic acid molecule which hybridizes to a transcript of the gene which use SEQ IN NO: 12, 14-18, 21-22, 24-25, 27 and 29, does not reasonably provide enablement for methods which use any nucleic acid molecule which hybridizes to a transcript of the gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Many nucleic acid molecules that hybridize to a transcript of the gene will not be an indicator of a human polypeptide having PI3 kinase activity and a molecular weight of about 110kD as determined by SDS-PAGE. The specification has only enabled methods which use the nucleic acid sequences set forth in SEQ ID NO: 12, 14-18, 21-22, 24-25, 27 and 29. The claims must recite SEQ ID NO's in the claims.

The claims broadly teach the contacting a sample with a nucleic acid molecule which hybridizes to a transcript gene, therefore any nucleic acid molecule is being claimed, where no specific nucleic acid molecule is recited and no specific hybridization conditions are taught. Therefore no specific method of determining expression of a gene is taught and enabled by the specification. Applicants have provided no guidance to enable one of ordinary skill in the art how to determine without undue experimentation the method for determining gene expression using every single nucleic acid molecule that could possibly hybridize to the transcript gene.

The specification does not provide guidance on how any nucleic acid molecule can be used nor does the specification provide guidance on how to determine which nucleic acid molecules will or will not hybridize. No working examples are shown containing the missing information. Without such information, one of skill in the art could not predict which nucleic acid molecules would hybridize to the transcript gene. Accordingly, one of skill in the art would be required to perform undue experimentation to use any nucleic acid molecule to determine the expression of a gene without any specifically recited hybridizing conditions. Therefore, one skilled in the art could not make and/or use the invention without undue experimentation.

6. Claims 27-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims vaguely recite hybridization. However the claims do not recite or define what reagents or components are required to necessitate hybridization conditions. Neither do the claims require any stringency levels to accomplish the hybridization. No stringency conditions or any other conditions were defined, the use of the PI3 kinase polypeptide of Skolnik et al., in view of Carpenter et al., thus the PI3 kinase of the prior art could hybridize in the claimed method.

Further, with respect to claims 32 and 33, DNA/RNA hybridization consist of allowing single stranded DNA or RNA to reassociate whereas any mismatch is presumably due to evolutionary divergence and will reduce bonding strength between the molecules. However, since

no stringency conditions or any other conditions were defined, the use of the PI3 kinase polypeptide of Skolnik et al., in view of Carpenter et al., could hybridize to any of the sequences disclosed in claims 32 and 33.

7. Claims 27-36 are again rejected for requiring the use of a nucleic acid molecule in a sample, however the nucleic acid molecule is undefined. The nucleic acid molecule is indefinite because it recites no limitations. Claim 27 broadly recites any nucleic acid molecule since the nucleic acid molecule is not defined by a particular sequence. Claims 32 and 33 recite specific nucleic acid molecules, however the SEQ ID NO:'s are not recited in claim 27.

Response to Arguments

8. Applicant's arguments filed December 11, 2001 have been fully considered but they are not persuasive.

9. Claim 36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained. The term any difference there-between is vague and indefinite because the term is not defined by the claim. The specification does not provide a standard for ascertaining the requisite degree of differences. Further, the specification does not teach what any difference can be. It is unclear how to define the any differences needed to be achieved when comparing the activity of the PI3 kinase agonist or antagonist. Thus one of ordinary skill in the art

would not be reasonably appraised of the scope of the invention. Therefore the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 27-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skolnik et al., in view of Carpenter et al., is maintained. Applicant argues that information relating to rat molecule that one of ordinary skill could reasonably expect to secure information relating to a human molecule. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been obvious at the time of applicants invention to have used the 110kD protein as taught by Carpenter et al., in the method of determining gene expression as taught by Skolnik et al., because Carpenter et al., teaches that the 110 kD protein was isolated by

SDS-PAGE, is correlated to the PI3 kinase activity, strongly related to cell growth activity, its gene products can be found of different genes and is crucial in intracellular signals which respond to a number of hormones and growth factors.

Further the claims broadly recite hybridization methods therefore, the DNA/RNA hybridization consist of allowing single stranded DNA or RNA to reassociate. However, since no stringency conditions or any other conditions were defined, the use of the PI3 kinase polypeptide of Skolnik et al., in view of Carpenter et al., could hybridize to the nucleic acid molecule recited in the claims.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines

February 20, 2001

JENNIFER GRASER 3/25/01
PATENT EXAMINER